

MAR 26 2002



K014236

### 510(k) Summary

**Submitter:** Clinicon Corporation  
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Carlsbad, CA 92008

**Contact person:** Sean M. Curry  
16787 Bernardo Center Drive, Suite A  
San Diego, CA 92128

**Phone:** (858) 675-8200  
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**Proprietary name:** Clinicon WaveGuide Platform with Interconnect for Luxar Accessories

**Common name:** CO<sub>2</sub> Laser Powered Surgical Instrument

**Classification:** 878.4810

**Product Code:** GEX

**Classification name:** Laser surgical instrument for use in general and plastic surgery and in dermatology.

**Substantial equivalence claimed to:**  
K992472, Clinicon's SureGuide CO<sub>2</sub> Laser Beam Delivery System  
K960475, Modified Luxar LX-20

### Description:

The Clinicon WaveGuide Platform (K992472, SureGuide CO<sub>2</sub> Laser Beam Delivery System now marketed as Clinicon WaveGuide Platform) is an accessory for CO<sub>2</sub> laser systems. Its two primary components are a laser system interface adapter and a fiber cable assembly consisting of a hollow silica fiber having an internal coating that reflects and propagates CO<sub>2</sub> laser energy and a flexible protective outer cover.

The WaveGuide CO<sub>2</sub> Fiber Cable has FSMA 905 series fiber optic connectors on each end and may be used with CO<sub>2</sub> laser systems that provide such connectors between the laser system and various beam delivery accessories.

The Clinicon Interconnect (Distal Adapter) is an accessory to the WaveGuide Platform that duplicates the termination end & laser beam characteristics of the Standard Luxar

Fiber. This allows Luxar accessories to be attached to the WaveGuide Platform and used in the same manner.

**Intended use:**

The intended use of the Clinicon WaveGuide Platform is to deliver carbon dioxide laser energy from a CO<sub>2</sub> laser source to a CO<sub>2</sub> laser accessory, with minimal beam degradation. The waveguide platform can be used with various manufacturers' CO<sub>2</sub> lasers and laser accessories, including Clinicon accessories. The specific indications are dependent upon the cleared indications for use of the laser system and laser accessories to which the waveguide platform is attached.

The Clinicon Interconnect (Distal Adapter) enables Luxar accessories that are designed to be used with the standard Luxar fiber cables to be connected with the Clinicon WaveGuide Platform.

**Summary of technological characteristics:**

The Clinicon WaveGuide Platform is an accessory for CO<sub>2</sub> laser systems. Its two primary components are a turret adapter and a fiber cable assembly. A secondary component is the Interconnect accessory.

The fiber cable assembly consist of a hollow silica fiber with an internal coating that reflects and propagates the CO<sub>2</sub> laser energy and a flexible protective outer covering. The fiber cable has a fiber optic connector on each end and may be used with CO<sub>2</sub> laser systems that provide such connectors between the laser system and various beam delivery accessories. The fiber cable is available in various standard lengths between 0.5 m and 3.0 m, and functions over the wavelength range of 9 – 11  $\mu$ m.

The Turret Adapter is the interface between the fiber cable and the CO<sub>2</sub> laser system, and houses a focusing lens to align the beam from the CO<sub>2</sub> laser system into the waveguide.

The Interconnect duplicates the distal termination end and laser beam characteristics of the Standard Luxar Cables. The Clinicon Interconnect contains a segment of the same coherent waveguide used throughout the Clinicon Waveguide Platform. Uniquely in the Interconnect, however, this waveguide segment is held in a manner that "scrambles" the spatial coherence of the input laser beam, so that the output laser beam is spatially incoherent. The particular distortion has been chosen so that the output of the Clinicon Fiber Cable with the Clinicon Interconnect has the same beam divergence and multimode character as does the output of the Luxar Fiber [cable]. This allows Luxar accessories to be used with the Clinicon Fiber Cable plus Clinicon Interconnect.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 26 2002**

Clinicon Corporation  
c/o Mr. Sean Curry  
Certified Software Solutions, Inc.  
16787 Bernardo Center Drive, Suite A  
San Diego, CA 92128

Re: K014236

Trade/Device Name: Clinicon WaveGuide Platform with Interconnect  
for Luxar Accessories

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: December 21, 2001

Received: December 26, 2001

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Sean Curry

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K014236

Device Name:

Indications for Use:

The intended use of the Clinicon WaveGuide Platform is to deliver carbon dioxide laser energy from a CO<sub>2</sub> laser source to a CO<sub>2</sub> laser accessory, with minimal beam degradation. The waveguide platform can be used with various manufacturers' CO<sub>2</sub> lasers and laser accessories, including Clinicon accessories. The specific indications are dependent upon the cleared indications for use of the laser system and laser accessories to which the waveguide platform is attached.

The Clinicon Interconnect enables Luxar accessories that are designed to be used with the standard Luxar cables to be connected with the Clinicon WaveGuide Platform.

Meriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K014236

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_